510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTER INFORMATION

A.	Company Name:	IntraLuminal Therapeutics, Inc.
B.	Company Address:	6354 Corte Del Abeto – Suite A Carlsbad, CA 92009
C.	Company Phone:	(760) 918-1820
D.	Company Facsimile:	(760) 918-1823
E.	Contact Person:	Pamela Misajon Vice President of Regulatory Affairs and Quality Assurance

DEVICE IDENTIFICATION

A.	Device Trade Name:	ILT Support Catheter and ILT Support Catheter Advancing Mechanism
B.	Catalog Number:	C114LW1 – ILT Support Catheter ~~A115AM1 – ILT Support Catheter Advancing Mechanism~~
C.	Device Common Name:	Percutaneous Catheter
D.	Classification Name:	Percutaneous Catheter
E.	Device Class:	Class II (per 21 CFR 870.1250)

IDENTIFICATION OF MODIFIED DEVICE

The ILT Support Catheter is a similar in design, materials, mode of operation and intended use to the IntraLuminal Therapeutics, Inc. ILT 0.014" Catheters cleared under 510(k) K001992. The modified device separates the catheter from the advancing mechanism.

DEVICE DESCRIPTION

The ILT Support Catheter is a single-lumen intravascular catheter intended for percutaneous use. It is designed to be used in conjunction with a 0.014" steerable guidewire to gain access to locations within the cardiovascular system that are remote from the site of insertion. Once accessed, guidewires may be exchanged within the catheter. The ILT Support Catheter may also be used for The ILT Support Catheter may also be used to provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

The effective length of the ILT Support Catheter is a nominal 135 cm. The nominal maximum outside diameter is 2.8 French (0.037"). The distal region incorporates a radiopaque material to aid in visualization under fluoroscopy. The inside diameter of the ILT Support Catheter shaft will accommodate a commercially available 0.014" guidewire.

~~The ILT Support Catheter Advancing Mechanism is a handle with a connecting luer in the distal side that can be mated to the ILT Support Catheter. The handle includes an advancing mechanism that allows for incremental advancement of the guidewire. This mechanism may be bypassed for free movements of the guidewire through the catheter shaft.~~

The ILT Support Catheter ~~and the ILT Support Catheter Advancing Mechanism~~ are packaged in a Tyvek® covered tray and heat-sealed to form a sterile barrier. The packaged catheter is sterilized by ethylene oxide gas. The ILT Support Catheter is provided "STERILE" and "Non-pyrogenic", and is intended for single use only.

INTENDED USE

The ILT Support Catheter is indicated to be used in conjunction with a steerable guidewire in order to access discreet regions of the vasculature. Once the region has been accessed, an exchange of one guidewire for another can occur. The ILT Support Catheter may also be used to provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

TECHNOLOGICAL CHARACTERISTICS

The ILT Support Catheter is similar in basic materials, design, construction and mechanical performance to the previously cleared ILT .014" Catheter. The modification separates the advancing mechanism (handle) from the catheter and allows the ability to use the ILT Support Catheter with or without the advancing mechanism..

BIOCOMPATIBILITY AND PERFORMANCE DATA

Biocompatibility testing and *in vitro* bench studies were conducted to evaluate the biological and performance characteristics of the ILT Support Catheter. Biocompatibility test results indicate that the device materials are biocompatible. Performance test results indicate that the device satisfies functional performance requirements when used as indicated.

CONCLUSIONS DRAWN FROM STUDIES

The results of testing demonstrate that the ILT Support Catheter with or with out the advancing mechanism is substantially equivalent to the predicate device and is capable of safely and accurately performing the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2001

Ms. Pamela Misajon
Vice President of Regulatory Affairs and Quality Assurance
IntraLuminal Therapeutics, Inc.
6354 Corte Del Abeto, Suite A
Carlsbad, CA 92009

Re: K012169
ILT Support Catheter and ILT Support Catheter Advancing Mechanism
Regulation Number: 870.1250
Regulatory Class: II (two)
Product Code: DQY
Dated: August 10, 2001
Received: August 13, 2001

Dear Ms. Misajon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K012169

Device Name: ILT Support Catheter (with or without Advancing Mechanism)

Indications For Use: The ILT Support Catheter with or without the advancing mechanism is indicated to be used in conjunction with a steerable guidewire in order to access discreet regions of the vasculature. Once the region has been accessed, an exchange of one guidewire for another can occur. The ILT Support Catheter may also be used to provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012169